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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,177	03/27/2002	Michel G Bergeron	1619.0090000/SRL/PJA	9698

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,177	BERGERON ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,29-37 and 39-48* is/are pending in the application.

4a) Of the above claim(s) *2-11,17-27,29-37 and 39-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 March 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

HL

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and SEQ ID NO: 664 and 697 in the reply filed on February 1, 2005 is acknowledged. The traversal is on the grounds that it would not impose a serious burden to examine all of the sequences as claimed. This is not found persuasive because a search of all of the claimed sequences together would in fact require undue burden. The claimed nucleic acids each consist of a distinct nucleotide sequence and thereby these nucleic acids do not share a common structure. Further, the nucleic acids have distinct melting temperatures and hybridization properties. The claimed nucleic acids hybridize with distinct target nucleic acids (**e.g.**, tuf, atpD, recA, tetM, rpoB, parC, blaTEM, embB, gyrA, gyrB, inhA, parE, blaSHV, vgbB, vatC, vatB, SatG, sulII, tetB gene sequences and different regions within these gene sequences), and detect the presence of different families, genera and species of microorganisms, algae, pathogens, parasites and fungi. Thereby, the sequences also do not share a common functional property. The specification discloses 2297 distinct nucleotide sequences. A search for each of the individual sequences is not co-extensive with one another. For example, a search in literature and sequence databases for the sequence of SEQ ID NO: 664 is not co-extensive with a search of, and would not lead one to all references which teach, the sequence of, for example, SEQ ID NO: 562. It is unclear as to the type of search applicants believe would allow one to search for SEQ ID NO: 664 and 697 and to simultaneously obtain all relevant references teaching the sequences of SEQ ID NO: 1-663, 665-696 and 698-2297.

Accordingly, the requirement is still deemed proper and is therefore made FINAL.

The claims of the non-elected inventions of Groups II and III, i.e., claims 4, 5, 8-11, 22-27, 31-37, and 39-43 are withdrawn from consideration.

Further, it is noted that claims 17, 19, 20, 21 and 48 are withdrawn from consideration as being drawn to a non-elected invention. In particular, the nucleic acids listed in claims 17, 19, 20, 21 and 48 do not include the elected Tuf nucleic acids of SEQ ID NO: 664 and 697. Claims 29 and 30 are also withdrawn from consideration as being drawn to a non-elected invention. These claims are directed to methods which detect specific antimicrobial resistance genes and toxin genes using the recited primers and thereby exclude the elected invention of detecting Tuf gene sequences, particularly using the primers of SEQ ID NO: 664 and 697.

In addition, claims 2, 3, 6, 7, 18, and 44-47 are withdrawn from consideration. These claims encompass an invention distinct from the elected invention in that they require the use of a non-elected sets of nucleic acids. It is noted that these claims encompass methods which require the use of SEQ ID NO: 694 and 697 in combination with a number of other non-elected nucleic acids. Since the independent claims and the elected invention is not allowable over the prior art, as set forth below, there is no special technical feature linking the claimed subject matter. As set forth in the MPEP (Annex B/Unity of Invention, Part I) "If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity a posteriori (that is, arising only after

assessment of the prior art) may be raised. Similar considerations apply in the case of a genus /species or combination /subcombination situation." In the present situation, there is no inventive link joining the claimed subject matter because the members of the Markush group do not share a common property or activity and do not share a common structure or are not alternatives belonging to a specific recognized class of compounds (i.e., do not behave in the same manner and cannot be substituted for one another). Thereby, the elected set of nucleic acids (i.e., SEQ ID NO: 664 and 697) is distinct from the sets of nucleic acids recited in claims 2, 3, 6, 7, 18, 21, and 44-48.

Accordingly, claims 1 and 12-16 have been examined herein. Claims 2-11, 17-27, 29-37 and 39-48 are withdrawn from consideration. Claims 28 and 38 have been canceled.

Specification

2. The disclosure is objected to because of the following informalities:

A. The specification refers to specific claim numbers. However, it is not proper to refer to claim numbers within the specification because the numbering of claims and the content of claims changes throughout prosecution as claims are amended, cancelled, withdrawn from consideration and renumbered prior to allowance. The specification should be amended to remove all references to specific claim numbers. See, for example, page 25 of the specification.

B. Portions of the text are missing from the headings in several of the tables – see, for example, pages 250, 253, 256, 330 and 335. The complete specification should be reviewed for any occurrences of missing text. Appropriate correction is required.

C. The specification is objected to because the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR ∋1.821(d). Figures 4 and 7 recite nucleic acid sequences. However, neither the drawings themselves nor the Brief description of the drawings provide the sequence identifiers for the recited sequences. Appropriate correction to add the SEQ ID NOs to the description of the drawings or new figures containing the SEQ ID NOs is required.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821-25 because the previously submitted Sequence Listing does not include each of the sequences set forth in the present application.

It appears that sequences recited in, for example, the tables on pages 273, 274-288, 291, 292, 294-300 of the specification are not present in the Sequence Listing. In addition, the specification appears to recite sequences that are the complements of larger sequences recited the sequence listing. However, a unique sequence identifier must be used for each sequence listed. Thereby, different sequence identifiers should be used for the original sequence and for the complementary sequence in those instances in which the complementary sequence is specifically recited.

As the sequence disclosures in this application are not pertinent to the claimed invention and in the interest of compact prosecution, this case has been examined on the merits. However, in response to this Office action, Applicants must comply with the requirements of 37 CFR 1.821-1.825. In particular, Applicant is required to submit a

new CRF and paper copy of the Sequence Listing containing the additional sequence, an amendment directing the entry of the Sequence Listing into the specification, an amendment directing the insertion of the SEQ ID NOs into the appropriate pages of the specification and a letter stating that the content of the paper and computer readable copies are the same.

4. The Drawings are objected to because there is a "crease" in the drawing pages, making portions of the drawing unreadable. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

5. Claim 1 is objected to because of the following informalities:

Claim 1 should be amended so that the sequence numbers are immediately adjacent to the recitation of "SEQ ID NOs:". For example, the claim should read: "...primer pairs defined in: SEQ ID NOs: 543, 556-561..., for generating a tuf/fus repertory; SEQ ID NOs: 562-574...for generating a atpD repertory..."

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 12-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite over the recitation of "primer pairs defined in" because it is not clear as to what is intended to be meant by this phrase. It is unclear as to whether this phrase refers to, for example, primers which comprise one of the recited sequences or primers which consist of one of the recited sequences.

Claims 12-16 are indefinite because the claims do not recite a clear nexus between the preamble of the claims and the method steps of the claims. The claims are drawn to methods for detecting the presence of a microorganism. However, the claims recite a final step of testing for hybridization of primers or probes to a test nucleic acid. The claims do not clarify how the step of testing for hybridization results in the detection of the presence of a microorganism. Thereby, it is not clear as to whether the claims are intended to be limited to methods of testing for hybridization of a primer or probe or methods for detecting the presence of a microorganism.

Claims 12-16 are indefinite over the recitation of "said group of microorganisms" because this phrase lacks proper antecedent basis.

Claims 12-16 are further indefinite over the recitation of "such as." A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by

such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 12-16 recite the broad recitation of "under specified conditions", yet the claims also recite under the conditions in which the primers and/or probes hybridize with tuf nucleic acids of a microorganism but do not detectably hybridize with nucleic acids from other microorganisms, which is the narrower statement of the range/limitation. Accordingly, it is unclear as to what is intended to be encompassed by the hybridization conditions. Further, the claims do not clearly set forth a distinction between the microorganisms and the "other microorganisms." Thereby, it is not clear as to what which microorganisms the probe hybridizes with and which microorganisms the probe does not hybridize with.

Claims 13 and 14 are indefinite over the recitation of "based on a nucleic acid target amplification method" (claim 13) and "based on a signal amplification method." It is not clear as to what is meant by a method being based on another method. That is, it is not clear as to whether, for example, the method comprises a target amplification or signal amplification method, or if the method comprises some unspecified variation of these methods, or whether the method does not in fact actually require a target amplification or signal amplification step.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergeron (WO 98/20157; cited in the IDS).

Bergeron teaches a method for generating a repertory of nucleic acids of tuf genes wherein the method comprises amplifying nucleic acids from a plurality of microorganisms using primers that amplify tuf gene sequences (see Example 1 and pages 11-12). In the method of Bergeron, the primers consist of sequences identical to present SEQ ID NO: 664 (referred to as SEQ ID NO: 107 in the reference) and present SEQ ID NO: 697 (referred to as SEQ ID NO: 108 in the reference). For example, Bergeron (page 11-12 and Table 13) teaches amplifying tuf nucleic acids from 54 distinct bacterial species using the primer pair of SEQ ID NO: 664 and 697. Accordingly, the method of Bergeron anticipates the invention of claim 1.

With respect to claims 12-16, Bergeron teaches methods for detecting the presence of a nucleic acid in a test sample wherein the methods comprise contacting a sample containing tuf nucleic acids with an oligonucleotide, allowing the oligonucleotide to hybridize to the test sample nucleic acids, and detecting hybridization between the oligonucleotides and the test sample nucleic acids (see, e.g., pages 23-25). Bergeron exemplifies methods in which the primers of SEQ ID NO: 107 and 108 (i.e., the primers identical to present SEQ ID NO: 664 and 697, respectively) are used to amplify and

detect the presence of bacteria in a test sample. The reference (page 24) teaches that the primers of SEQ ID NO: 107 and 108 do not amplify nucleic acids of non-bacterial origin. Thereby, the conditions of hybridization are such that the primers hybridize to only one group of microorganisms (bacteria) and not to other groups of microorganisms (non-bacteria). Bergeron (page 24) further teaches methods for detecting the presence of *Enterococcus* wherein the methods comprise contacting a test sample with a primer pair that hybridize with tuf nucleic acids, amplifying test sample nucleic acids with the primer pair and detecting the amplification products as indicative of the presence of *Enterococcus* species. The *Enterococcus*-specific primers did not amplify bacteria from other species. Similarly, Bergeron (page 24) further teaches methods for detecting the presence of Staphylococcus wherein the methods comprise contacting a test sample with a primer pair that specifically hybridizes to *Staphylococcus* tuf nucleic acids, amplifying test sample nucleic acids with the primer pair and detecting the amplification products as indicative of the presence of *Staphylococcus* species. The reference also teaches methods for detecting the presence of *Candida albicans* wherein the methods comprise contacting a test sample with a primer pair that specifically hybridizes to *Candida albicans* tuf nucleic acids, amplifying test sample nucleic acids with the primer pair and detecting the amplification products as indicative of the presence of *Candida albicans* species. With respect to claims 13 and 14, Bergeron teaches that the detection of hybridization of the primer to the target nucleic acid is accomplished by target amplification methods, such as PCR or ligase chain reaction, or signal amplification methods, such as branched DNA signal amplification (see, e.g., pages 7 and 29).

With respect to claims 15 and 16, the methods exemplified by Bergeron include the use of primers that are both fully complementary and partially complementary to the target nucleic acids (see pages 11 and 23-25). Accordingly, the methods of Bergeron anticipate the invention of claims 6-12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
April 20, 2005

CARLA J. MYERS
PRIMARY EXAMINER

Notice to Comply	Application No. 10/089,177	Applicant(s)	
	Examiner	Art Unit	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: Amino acid sequences listed in claims 27-28 should be identified by a sequence identifier.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

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